

## **DETAILED ACTION**

### **Supplemental Final Rejection**

**Notice:** Upon further consideration, the new claims 39-44 have been reconsidered and rejected under 102. The previous Final Office Action mailed on 11/16/07 has been vacated; the following Final Office Action is applied.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11, 13-17, 21, 23, 24, 26-30, 32, 34, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyce et al (USPN 6,294,041 hereafter '041). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.
3. The '041 patent teaches an osteoimplant comprising calcium phosphate, active agents and other common ingredients (abstract). The implant comprises bioabsorbable polymers and excipients such as starches, polymethyl methacrylates, polyethylene and other common polymers (col. 4, lin. 25-40). The implant further comprises bioactive compounds such as antiviral agents, and biological compounds such as stem cells and collagen, along with various growth factors (col. 4, lin. 60-col. 5, lin. 15). The implant is applied to an injured or defective area in order to

repair the effected area (col. 5, lin. 65-col. 6, lin. 25). The collagen is surface bonded to the implant (col. 6, lin. 26-35). The composition is present in various forms including fibers (example 1). Theses disclosures render the claims anticipated.

4. Claims 11-14, 26, 27, 28, 30, 31, and 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (USPN 6,027,742 hereafter '742). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The claims are also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

5. The '742 patent teaches a bioresorbable ceramic composite comprising calcium phosphate and other materials (abstract). The composite comprises collagen, demineralized bone and other natural material I (col. 9, lin. 45-48) as well as polymers such as polyesters of carboxylic acids (col. 9, lin. 50-55). The further includes harvested cells that are seeded into the implant and proliferate at the implantation site (col. 12, lin. 10-22). The composites are formed by well-known methods including mixing, blending and alloying (col. 13, lin. 62-65). The particles produced range in size from 25-200 microns (example 6). These disclosures render the claims anticipated.

6. Claims 11, 12, 17-19, 30, 33, 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Marotta et al (USPN 5,990,380 hereafter '380). The claims are drawn to a composite material comprising a calcium and phosphate molecule along with various active and inactive ingredients. The composite comprises fibers that are equally spaced. The claims are

also drawn to a method of repairing tissues using the composite material, as well as a method making the composite by mixing the ingredients together.

7. The '380 patent teaches a bioglass implant comprising calcium and phosphate molecules in a composite with others compounds (abstract, table 1). The particles are below 100 microns (col. 6, lin. 5-12) and are present in fibers that are spaced from 20-200 microns apart (claims, examples). The composite is formed at room temperature by mixing the components (examples). These disclosures render the claims anticipated.

8. Claims 11-13, 21, 22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ducheyne et al (USPN 5,676,720 hereafter '720). The claims are drawn to a composite material comprising a bioglass and biologically active agents. The composite is delivered for sustained release profile.

9. The '720 patent teaches a porous bioglass composite comprising calcium and phosphate molecules (abstract) and other compounds (claims). The composite encapsulates an active agent such as a cell on its surface and is implanted allowing for sustained interaction with the defective implant area (col. 8, lin. 44-65). These disclosures render the claims anticipated.

10. Claims 11 and 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Janas et al (US 2001/0016353 hereafter '353). The claims are drawn to a bioactive glass composite comprising a biocompatible polymer and a bioactive glass comprising calcium and phosphate.

11. '353 patent teaches a bioactive glass composite comprising bioactive glass comprising calcium phosphate [0030], along with biocompatible polymers [0029]. The composite comprises

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at least one gelled alkoxysilane [0018]. The bioglass composite material also comprises a biocompatible polymer such as gelatin [0038]. The sol-gel derived composite is amorphous in structure and can be used as a scaffold for carrying biologically active compounds [0038, examples]. For these reasons at least the '353 patent anticipates the instant claims.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 11,20, and 36-38 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Niederauer et al (USPN 6,344,496 hereafter '496). The claims are drawn to a bioglass composite comprising a calcium and phosphate molecule along with other common excipients. The composite has a porosity of at least 50%. The claims further recite a method of making the composite where the temperature is below 200 degrees Celsius and the composition is sprayed or extruded.

13. The '496 patent teaches a bioglass composite comprises a calcium and phosphate bioglass compound (col. 4, lin. 19-38). The composite further comprises polymers known in the art such as polyglycolide and glycolide/lactide copolymers (col. 5, lin. 62-col. 6, lin. 18). The

composite is used as an implantable device (col. 6, lin. 49-59). The porosity of the composite is between 60-90 % (col. 8, lin. 5-15). The composite is formed at room temperature and is spray-dried (examples). These disclosures render the claims anticipated.

***Response to Arguments***

14. Applicant's arguments filed 8/23/07 have been fully considered but they are not persuasive. Applicant argues that:

- a. The Boyce reference does not anticipates the claims since it does not disclose a true glass as instantly claimed.
- b. The Lee reference does not anticipate the claims since it does not disclose a true glass as instantly claimed.
- c. The Marotta reference does not anticipate the claims since it does not disclose the sol-gel process of the instant claims.
- d. The Ducheyne reference does not anticipate the claims since it does not discloses a sol-gel processing steps as instantly claimed.
- e. The Niederauer reference does not anticipate the claims since it does not disclose a continuous sol-gel process of the instant claims.

15. Regarding argument a., it remains the position of the Examiner that the Boyce patent anticipates the claims. Applicant argues that the claims are drawn to a true glass as defined by Merriam-Webster Online Dictionary. Applicant argues that these true glasses are different and distinct form the bio-glasses of the prior art. However Applicant specification at paragraph [0055] states that: "the term "bioglass" refers to those materials, including BIOGLASS". Further

according to the definition of the true glass, the material is formed from a melt procedure. The composite of the instant claims, according to the specification is not formed from a melt procedure but rather a sol-gel procedure, a separate and distinct procedure. The claims are drawn to a composite material, not a process of making such. As such the claims are defined by their components, namely a biocompatible polymer and a bioactive glass including at least one calcium and one phosphorous molecular species. The implants of the Boyce patent are demineralized bone materials that have tri-calcium phosphate added as a filler material along with biocompatible polymers such as bioglass, starches, polyglycolide polylactides and polymethyl methacrylate (col. 4, lin. 25-35). Though the implant is bone derived and demineralized (minerals such as calcium removed via an acid process), the added fillers that include bioglass and tri-calcium phosphate and other biocompatible polymers meet the limitations of the claims. Applicant argues that the invention lacks crystallinity however this is not reflective in the instant claims. The claims are drawn to a bioglass composite comprising a bio glass and a biocompatible polymer. The Boyce patent meets the limits of the claims and therefore anticipates the claims.

16. Regarding argument b., it is the position of the Examiner that the Lee patent anticipates the claims. Applicant continues to argue that the claims recite a true glass composite, however according to the specification bioglass materials meet the limitations of the invention. The claims require a biocompatible polymer, a bioglass material, a calcium and phosphorous molecule. The patent discloses a bioresorbable polymer implant with low crystallinity, calcium phosphate and a supplementary material (abstract). The supplemental materials include biocompatible polymers such as bio active glass compositions include calcium, silicon and phosphorous oxide (col. 9, lin.

55-63) and polyglycolide polymers (col. 9, lin. 40-55). These disclosures meet the limitations of the claims. The Lee patent discloses harvested cells, particles and a method of making including mixing, blending all meeting the limitations of the claims (col. 12, lin. 10-22; col. 13, lin. 62-65 and example 6). Each of these disclosures renders the claims anticipated.

17. Regarding argument c., it remains the position of the Examiner that the disclosures of the Marotta patent anticipate the claims. Applicant argues that the prior art does not disclose the sol-gel continuous process of the instant invention. However the claims do not recite a continuous sol-gel process. The claims recite a mixing process for making the composite comprising mixing and hydrolyzing the mixture. The Marotta patent discloses this process along with a disclosure of the spacing of the imbedded fibers (claims). These disclosures render the claims anticipated.

18. Regarding argument d., it is the position of the Examiner that the patent continues to anticipate the claims. Applicant argues that the invention of the Ducheyne patent does not disclose a composite as described in the instant claims. During processing the bioactive glass components are mixed with binders such as polyvinyl alcohol, a biocompatible polymer (col. 6, lin. 15-24). These disclosures meet the limitations of the claims.

19. Regarding argument e., it is the position of the Examiner that the Niederauer patent anticipates the claims. The patent discloses a bioactive glass composite comprising bioactive glass components combined with biocompatible polymers (abstract, col. 4, lin. 19-27; col. 5, lin. 63-67). Again applicant argues the crystallinity of the composition in that the patent is drawn to a ceramic while the invention is a true glass. These crystalline features are not represented in the claims. As discussed above, the specification recites that BIOGLASS materials meet the limitations of the invention. Irrespective of crystallinity these compounds meet the limitations of

the bioactive glass limitations. The process of the instant claims requires mixing and hydrolyzing. There is no gelling involved. The Niederauer patent anticipates the process of the instant claims (examples).

20. For these reasons at least the discussed patent continues to anticipate the instant claims.

***Conclusion***

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young  
Examiner  
Art Unit 1618

/Micah-Paul Young/  
Examiner, Art Unit 1618

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618